Remarks

Claims 1-19 are pending.

Claim 6 stands rejected under 35 U.S.C. § 112, second paragraph as failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kumta et al., U.S. Patent No. 7,247,288, in view of Nagata et al., U.S. Patent No. 5,427,754.

Claims 5-8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kumta in view of Wong et al., U.S. Publication No. 2003/0017189, and Sikes, U.S. Patent Nos. 5,051,401 and 4,603,006.

Claims 1 and 9-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Itoi, U.S. Patent No. 6,159,437, in view of Kumta.

Claims 14-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kumta in view of Itoi.

Claim 6 has been amended to delete the word "type" from the claim when referring to the polymers or copolymers that may be included in the invention. No new matter is added.

The applicant respectfully maintains that the Examiner has failed to establish a prima facie case of obviousness in this case. It is well recognized that the chemical arts are generally unpredictable, as recently confirmed by the Federal Circuit in Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353 (Fed. Cir. 2008)("To the extent that an art is unpredictable, as the chemical arts often are, KSR's focus on these 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable."). One skilled in the art would not have predicted the results achieved by the applicant based on the information available in the references cited by the Examiner. Accordingly, the combination suggested by the Examiner does not establish that the claimed composition is obvious. See

"Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of Supreme Court Decision in KSR International v. Teleflex, Inc.", 72 Fed. Reg. 57,526 (October 10, 2007)(in order to establish obviousness, must show a combination of prior elements according to known methods to yield predictable results).

In the KSR case, the Supreme Court confirmed the application of the factors set forth in Graham v. John Deere Co., 383 U.S. 1 (1966), in determining whether a claimed invention is obvious. Under Graham, one must consider the scope and content of the prior art and the differences between the prior art and the claims at issue to determine if an invention is obvious.

Scope and Content of the Cited Art

Kumta, U.S. Patent No. 7,247,288, describes a method for producing nanocrystalline hydroxyapatite particles having a diameter in the range of about 1 nm to about 100 nm. Col. 8, lines 19-22. The hydroxyapatite particles are produced by combining calcium and a non-ionic phosphate, such as trisodium phosphate, in the presence of hydroxyl ions, such as from sodium hydroxide. Col. 8, lines 1-4, Example 1. The reaction is carried out with calcium ions far outnumbering phosphate ions in the reaction solution. Col. 4, lines 47-54; col 8, lines 6-9. According to Kumta, the initial pH of the solution is about 12, and decreases only slightly after the reactants are combined. Col. 15, lines 47-67 and Fig. 1.

Kumta also describes incorporating the hydroxyapatite particles produced from the process into a substrate or depositing the hydroxyapatite particles on a substrate. Col. 8, lines 44-49. The substrate may be a "matrix, such as a biomimetic extracellular matrix, which a is synthetic matrix that is intended to mimic a natural extracellular matrix in it structure and/or function." Col. 8, lines 49-53. Kumta states that the matrix may be a natural or synthetic polymer. Col. 8, lines 53-55.

Nagata, U.S. Patent No. 5,427,754, describes production of a "platelike" hydroxyapatite produced by mixing a phosphate, a calcium and water to form an aqueous slurry of calcium phosphate. Col. 9, lines 9-34. Nagata does not describe any pH control for production of the slurry. The calcium phosphate slurry is subjected to a hydrothermal treatment in the presence of an alcohol. The aqueous slurry and alcohol mixture is heated to a temperature of between 120° to 200°C for a period of 2 to 20 hours to convert the calcium phosphate to hydroxyapatitde. Col. 2, lines 35-58.

Nagata states that the hydroxyapatite produced by the process are "approximately hexagonal plates grown along their a and b axes." Col. 2, lines 65-68. The size of the hexagonal plates are "generally in the range of approximately 50 to 200 nm." Col. 3, lines 1-2. Nagata does not describe the thickness of the hexagonal plates. In addition, Nagata does not describe a hydroxyapatite combined with at least one polymer.

In Comparative Experiments 1 and 2 in column 4, Nagata describes production of rod-like or needle-like hydroxyapatite structures. These structures are not platelets, and Nagata describes the structures as "measuring about 100 nm in size" without specifying whether this is the length, diameter or both.

Wong, U.S. Publication No. 2003/0017189, describes an active agent dosage form for prolonged delivery of a liquid, active agent formulation. Paragraph [0049]. Referring to Fig. 1 of Wong, the dosage form generally comprises porous particles (12) having pores (13) in which the liquid, active agent (14) is absorbed. Paragraph [0064]. The particles are dispersed within a polymer matrix (11).

As described in Wong at Paragraphs [0067] and [0068], the particles may be formed from a spray dried monetite material to form spherical particles having a mean particles size of at least 50 microns and usually about 70-130 microns. Wong emphasizes the importance of spherical particles because they provide excellent flow properties and permit direct compaction into tablets.

Sikes, U.S. Patent No. 4,603,006 ("Sikes '006"), describes the use of polysaccharide derivatives to inhibit formation of calcium carbonate scales on surfaces from calcium carbonate plants and animals. Col. 4, lines 56-68. The monosaccharide polymers described in Sikes '406 inhibit formation of calcium carbonate crystals. Col. 7, lines 1-12. Sikes does not describe calcium phosphates at all.

Similarly, Sikes, U.S. Patent No. 5,051,401 ("Sikes '401") describes phosphorylated, polyanionic peptides "that are surprisingly powerful inhibitors of mineral formation, particularly the crystallization of calcium carbonate and calcium phosphate." Col. 1, lines 13-18. Sikes '401 lists numerous uses for the polymers to prevent formation of calcium phosphate in various biological applications. Col. 3, lines 41-46. Accordingly, the polymers described in Sikes '401 actually prevent the formation of calcium phosphate crystals such as those recited in claims 1-19.

Itoi, U.S. Patent No. 6,159,437, describes an apatite slurry comprising a water soluble organic solvent to disperse apatite particles in the liquid slurry such that the average apatite particle-size is less than 1 micron. The slurry is formed by reducing the size of larger apatite particles contained in a water-compatible organic solvent by means of an agitation mill. Col. 2, lines 6-9. Itoi does not describe compositions comprising calcium phosphate platelets and polymers as recited in claims 1-19.

Differences Between Prior Art and Claims At Issue

Claim 1 recites a colloidal dispersion of calcium phosphate platelets wherein the length of the platelets, L, is between 5 nm and 500 nm and the thickness of the platelets is between 0.5 and 20 nm, and at least one polymer that complexes calcium. As set forth in the application in Paragraph 0024, "platelets" refers to bar or strip shapes and more generally any volume which has a low thickness and a greater length than width.

Kumta describes calcium phosphate particles having a diameter in the range of about 1 nm to about 100 nm. Particles are generally approximately spherical in shape, consistent with the description in Kumta of the particles as having a diameter (as opposed to a length, width or thickness). Particles are not platelets as described in the present application and recited in claim 1 as amended.

Moreover, Kumta does not describe a colloidal dispersion comprising calcium phosphate platelets and at least one polymer which complexes calcium as recited in claim 1. Rather, Kumta describes a matrix that is intended to mimic a natural extracellular matrix in structure or function. The matrix may be a natural or synthetic polymer. A matrix for use in biomedical applications is very different from the polymer claimed in the present application.

Nagata describes "hexagonal plates" of calcium phosphate "generally in the range of approximately 50 to 200 nm." Nagata does not describe the shape of the hexagonal plates other than that they are grown along the a and b axes of a hexagon. Nagata does not describe the thickness of the hexagonal calcium phosphate plates at all. It does not appear that the hexagonal plates of Nagata, which are formed by a very different process than the platelts of the present invention, are "platelets" as defined in Paragraph 0024 of the specification. In addition, Nagata

does not describe a calcium phosphate platelet combined with at least one polymer which complexes calcium as recited in claim 1 of the application.

Combining Kumta with Nagata does not result in a composition of claim 1. Kumta describes calcium phosphate particles, and Nagata describes hexagonal plates without any description of the length, width or thickness of the plates. Neither reference describes calcium phosphate platelets, as described in the application, in combination with a polymer which complexes calcium as recited in claim 1. Accordingly, claim 1, and claims 2-4 which depend from claim 1, are not obvious in view of Kumta and Nagata for at least these reasons, and the rejection of claims 1-4 under 35 U.S.C. § 103(a) should be withdrawn.

Wong, like Kumta, describes spherical calcium phosphate particles. In Paragraph 0067, Wong emphasizes the importance of the spherical shape for use in the dosage forms described due to flow properties and the ability to compact the spheres. Neither Wong nor Kumta describe calcium phosphate platelets as recited in claim 1.

Likewise, neither Sikes '006 nor Sikes '401 describes calcium phosphate platelets. Sikes '006 is not directed to calcium phosphate at all, and instead is directed to monosaccharide polymers that inhibit formation of calcium carbonate scales. Sikes '401 is directed to peptides that inhibit crystallization of calcium phosphate. One skilled in the art would not be motivated to use polymers that inhibit formation of crystals in a composition with calcium phosphate. Indeed, this teaches away from the use of the polymers described in Sikes '006 and Sikes '401 with the calcium phosphate platelets recited in claim 1. MPEP 2141.02(VI).

Claims 5-8 all depend from claim 1. Because none of Kumta, Wong or Sikes describes calcium phosphate platelets as recited in claim 1, the rejection of claims 5-8 under 35 U.S.C.

§ 103(a) should be withdrawn for at least this reason. MPEP § 2143.03 (if an independent claim is nonobvious under 35 U.S.C. § 103, then all claims depending from that claim are nonobvious). In addition, because Sikes '006 and Sikes '401 describe polymers that inhibit formation of calcium carbonate and calcium phosphate crystals, one skilled in the art would not combine Sikes '006 or Sikes '401 with Kumta and Wong to arrive at the composition recited in claim 1 and claims 5-8, and the rejection of claims 5-8 under 35 U.S.C. § 103(a) should be withdrawn for this additional reason.

Itoi describes an apatite slurry containing apatite particles having an average particle size of less than 1 micron. As discussed above, Kumta describes spherical calcium phosphate particles. Neither Itoi nor Kumta describe calcium phosphate platelets as recited in claim 1. Accordingly, the rejection of claims 1 and 9-13, which depend from claim 1, based upon Itoi in view of Kumta should be withdrawn for at least this reason. MPEP § 2143.03

Claim 14 describes a process for producing a dispersion of calcium phosphate platelets and at least one polymer which complexes calcium. The process of claim 14 requires that the pH of the solution in which the calcium phosphate platelets is formed must be adjusted to a selected value between 4 and 6 and maintained at the selected value between 4 and 6 while the calcium phosphate platelet dispersion is formed.

Kumta describes a process for producing calcium phosphate particles in a solution having an initial pH of 12 that decreases only slightly during the process. Itoi describes formation of an apatite slurry by mixing agglomerated apatite to create particles of apatite in water. Itoi does not even discuss pH, much less describe or suggest the pH limitations recited in claim 14. Neither Kumta not Itoi describe or suggest a process for producing a calcium phosphate dispersion in

which the the solution in which the calcium phosphate platelets is formed must be adjusted to a selected value between 4 and 6 and maintained at the selected value between 4 and 6 while the calcium phosphate platelet dispersion is formed. Accordingly, the combination of Kumta and Itoi does not result in a process meeting all of the limitations of the claims, and the rejection of claims 14-19 based upon Kumta and Itoi should be withdrawn for at least this reason.

In view of the amendments to the claims and the foregoing remarks, the pending claims are believed to be allowable over the prior art of record. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance issued. If the Examiner believes that a telephone conference with Applicants' attorney would be advantageous to the disposition of this case, and in particular if a terminal disclaimer is required for allowance, the Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

A Petition for a Three Month Extension of Time along with the associated fees are filed herewith. No additional fee is believed to be required. In the event the Commissioner of Patents and Trademarks deems additional fees to be due in connection with this application, Applicant's

attorney hereby authorizes that such fee be charged to Deposit Account No. 50-3569.

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